Norfolk Medical

7350 N. Ridgeway, Skokie, IL 60076 • 847-674-7075

K111101

Section 5

AUG 25 2011

510(k) Summary

NorPort CT·PC Port Family of Implanted Vascular Access Devices, and Lucent Non-Coring Needle Infusion Set

510 (k) Summary of Safety and Effectiveness Information 21 CFR 807.92

Part I
General Information

5.1 Submitter/Sponsor Information

Submitter Name:	Norfolk Medical Products, Inc.
FDA Establishment Registration Number:	1450392
Address:	7350 N. Ridgeway Skokie, IL 60076
Telephone Number:	(847) 674-7075
Fax Number:	(847) 674-7066
Contact Person:	Michael J. Dalton/President
Date of Preparation:	April 15, 2011

5.2 Device Name

Device Name:	Implanted Drug Delivery Device (Port) and Huber Needle Intravascular Administration Set (Needle)
Trade Name:	NorPort CT·PC Family of Ports and Lucent Non-Coring Needle Infusion Set
Device Common or Usual Name:	Implantable Infusion Ports and Intravascular Administration Set

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Classification Name:

Catheter/Port:

LJT- Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965- Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II

Needle:

FPA- Huber Needle Intravascular Administration Set 21 CFR 880.5440- Intravascular Administration Set

5.3 Predicate Device Name

Catheter/Port:

Device Name:	Norfolk Medical NorPort Port
Premarket Notification:	510 (k)# 102385, 2010
Device Name:	Bard Power Port Titanium Port w/8Fr
Premarket Notification:	510 (k)# 060812, 2006
Device Name:	Smiths Medical PORT-A-CATH Titanium Venous Access System
Premarket Notification:	510 (k)# 070116, 2007
Device Name:	Angiodynamics Smartport CT Series Port Access System
Premarket Notification:	510 (k)# 081472, 2008
Device Name:	PHS C-Port^{HP} "Power Injectable" Port
Premarket Notification:	510 (k)# 091099, 2009
Device Name:	MEDCOMP ProFUSE^{CT}
Premarket Notification:	510 (k)# 070003, 2007

Needle Infusion Set:

Device Name:	Smiths Medical Gripper Plus Power P.A.C Needle
Premarket Notification:	510 (k)# 070116, 2007
Device Name:	Angiodynamics Lifeguard CT Safety Infusion Set
Premarket Notification:	510 (k)# 072375, 2007
Device Name:	Bard PowerLoc Clear Safety Infusion Set
Premarket Notification:	510 (k)# 082306, 2008
Device Name:	MEDCOMP CT Injectable Safety Huber Needle
Premarket Notification:	510 (k)# 080544, 2008

5.4 Device Description

NorPort CT·PC Port Family of Implanted Vascular Access Devices:

The Norfolk Medical NorPort CT·PC Port is composed of a port reservoir with an attachable catheter system. The Port reservoir consists of a titanium or polysulfone chamber with a silicone septum and an outlet pin (510 (k)#102385). The silicone septum is designed to allow multiple needle puncturing while maintaining the leak-tight integrity.

The NorPort CT·PC comes in standard design to enable regular use as an infusion/withdrawal port and has high-pressure injection capability to aid in the delivery of large volumes of specialty fluids such as contrast media. The NorPort CT·PC is triangular shaped with a recessed septum ring. The body port has a "CT" symbol machine etched on the bottom end to enable easy recognition of the port with most imaging systems. The port has 3 holes for suture fixation to the tissue. A catheter comes with the port and is inserted in the vascular system. The catheter is usually inserted into a venous vessel and fed down into the superior vena cava. The placement of the catheter is checked by radiographic technique. The catheter is radiopaque to enable visualization for placement. The kit provided to aid in insertion of the catheter and placement of the port may include introducer items like needles, sheathes, vein picks, guidewires, straighteners, and dilators. Likewise the, "cut-down", kit for port placement may contain tunnelers, infusion sets with 90 degree Huber point needles, and syringes along with the port and catheter.

Lucent Non-Coring Needle Infusion Set:

The Lucent Non-Coring Needle Infusion Set is similar to the following predicate devices: Smiths Medical Gripper Plus Power P.A.C Needle (510 (k)# 070116), the Angiodynamics Lifeguard CT Safety Infusion Set (510 (k)#072375), the Bard PowerLoc Clear Safety Infusion Set (510 (k)# 082306), and the MEDCOMP CT Injectable Safety Huber Needle (510 (k)# 080544). The Lucent Non-coring and the predicated devices are supplied sterile and non-pyrogenic and are intended for the administration into or withdrawal of fluids from the Norfolk Medical line of implanted ports. When a "Power Injectable" NorPort CT-PC Port is used, the Lucent Non-coring and the predicate devices are indicated for power injection of contrast media.

5.5 Indications for Use Statement and Product Function

Catheter/ Port:

The NorPort CT·PC Family of Implanted Vascular Access Devices is indicated for use when the patient requires repeated access to the vascular system for injections, infusion drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen.

The NorPort CT·PC Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 and 20 gauge non-coring power injectable needle and 2 ml/s with a 22-gauge non-coring power injectable needle.

Needle:

The Lucent Non-Coring needle Infusion Set is intended for the administration of fluids and drugs as well as blood sampling through implanted vascular ports.

When used with the NorPort CT·PC Family of Implanted Vascular Access Devices, the Lucent Non-Coring Needle Infusion Set is also indicated for power injection of contrast media into the central venous system.

5.6 Contraindications or Cautions for Use

A detailed list of possible implantation complications and contraindications of the NorPort CT·PC family of ports are listed in the "User's Manual" which is supplied with each NorPort CT Kit. Some of the possible complications due to the implantation of the Norport CT·PC include, but are not limited to, infection, occlusion, embolization, catheter fragmentation, erosion, extrusion of the device, hematomas, clot formation and thrombosis.

Improper placement of the catheter in the body has been shown to cause the catheter to be cut off from a, "pinching" effect by the clavicle and the first rib. Exercise caution when placing the catheter into the vein and the superior vena cava to ensure that the catheter does not pass between the juncture of the clavicle and the first rib. This "Pinch-off" complication is well documented and a well understood potential complication of the surgical implantation of the Port system.

5.7 Methods of Application

The method of application is to prepare and insert the catheter into the vein (using "cut down" method or "percutaneous" method) and on into the junction of the superior vena cava and the right atrium. Then the proximal end of the catheter is tunneled subcutaneously to an area of cut down where the port is to be placed beneath the skin and secured to the muscle tissue. The catheter is joined to the port and the port is sutured to the muscle. All incisions are sutured normally by the physician.

Intravenous fluids, medications, blood products, or nutritional fluids may then be administered by needle puncture of the septum in the port or periodic blood samples may be acquired if appropriate flushing techniques are followed. A complete description of the uses of the port is contained in the Instructions for Use/User's Manual in Appendix B.

When used with a power injectable needle infusion set, the NorPort CT·PC Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 and 20 gauge non-coring power injectable needle and 2 ml/s with a 22-gauge non-coring power injectable needle.

5.8 Special Precautions for Disposal

Any sharp instrument used in the procedure should be properly disposed of according to the institution policy. Any remaining parts or empty packages do not require special handling when disposing.

5.9 Sterilization Information

The NorPort CT·PC Port and the Lucent Non-coring needle infusion set are provided sterile and are recommended for single use only. In the event that the product becomes contaminated (not by bodily fluids or tissue) prior to use, replace it with sterile product and return the device to Norfolk Medical for repackaging and re-sterilization.

5.10 Validity Period

As long as the package remains unopened and undamaged the product is valid for use. The materials included with the NorPort kit, the Lucent Non-coring needle and the NorPort CT·PC Port do not degrade over time.

5.11 Special Precautions for Handling and Storage

Products should be stored in a cool and dry place. It should only be open prior to use.

5.12 Description of Package (NorPort CT·PC Port Kit)

The NorPort CT·PC Port Kit includes a port and catheter and the following inside the sterile package:

- 1 Non-coring Point Needle (straight needle)
- 1-Vein Pick (retraction/introduction device)
- 1- Tunneling trocar (atraumatic tip)
- 1- Blunt needle
- 1-10 mL syringe
- 1- Locking Mechanism
- 1- Patient chart Sticker
- 1- User's Manual

The plastic tray is contained within a heat-sealed polyethylene/nylon Tyvek® header bag (pouch) and sterilized. If requested a percutaneous introducer kit is included in the NorPort CT·PC Port kit package. This Port/Introducer Kit is listed with its own catalog number. This kit might be ordered separate or as part of the kit as requested by the physician.

The percutaneous introducer kit, or "Full-Kit" as described in the brochure and catalog, contains the following:

- 1- Basic set
- 1- "Split Sheath" percutaneous introducer
- 1- J-Flex guide wire with thumb advancer
- 1- Introducer needle

In addition, the NorPort CT·PC Port "Full-Kit" is packaged with a "User's Manual" and "Patient Implant" stickers.

Each Kit is packaged in an external fiberboard box. Each box is labeled accordingly to match the item inside the box.

5.13 Labeling

All products are properly labeled on its plastic container with a stick on label containing the following information. Refer to appendix C for sample labels.

- Company Name, Address and Contact Number
- Product Name (Brand Name and Common Name
- Catalog Number
- Catheter Size
- Lot Number
- Units included
- Restricted Device Note: Federal Law restricts this device to sale by or on the order of a physician
- Sterile unopened undamaged package
- For single use only statement

5.14 Instruction for Use

Note: Detailed instructions for use and care of the NorPort CT·PC are in the "USER'S MANUAL. A simple listing of implant instruction is listed here:

1) Before implanting inspect the port thoroughly. Do not use if holes, cracks, or surface contaminations are present.

2) Flush all air from the port prior to placement using the 20ga Non-coring point needle and syringe with heparinized saline, which is provided with the kit.

3) The selected site for the reservoir body should be over a bony structure and in a location that is convenient and comfortable for the patient.

4) Place the catheter into the vein using the "cut-down" technique or by using a percutaneous introducer.

5) Place the tip of the catheter in an area of high blood flow when placing it in the venous system. Fluoroscopy is highly recommended to verify proper placement of the catheter tip in the junction of the superior vena cava/high right atrium.

6) Take special care not to serrate the catheter tip or occlude it during the catheter placement process. Leave sufficient slack upon placement so the patient movement does no stress the catheter.

7) Position the pocket for the reservoir so that the suture line is not directly over the port. Do not place the port too deep or to shallow. A depth of approximately 5mm under the skin surface is recommended as the optimal placement of depth.

8) Cut the catheter to the proper length and moisten all components with saline.

9) Slide the catheter lock over the catheter.

10) Slide the catheter over the barbed outlet tube (pin connector) of the reservoir.

11) Slide the catheter lock and catheter forward until the catheter and the outlet tube are completely covered.

12) Test the connection by gently tugging on the catheter.

13) Secure the port to the underlying fascia with at least three non-absorbable sutures.

14) After suturing has been satisfactorily completed, flush the incision with an appropriate antibiotic to ensure a sterile pocket.

15) Before closure, check patency and flow through the NorPort CT·PC Port by x-ray, fluoroscopy, or by imaging technique of choice.

16) After each use, always leave the NorPort CT·PC Port filled with a heparinized saline solution in a concentration recommended by your institution.

17) When the NorPort CT·PC Port is to be used for "power injection" of special fluids, a power injectable needle infusion set must be used. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19 or 20 gauge non-coring power injectable needle and 2 ml/s with a 22 gauge needle.

A copy of the Instructions for Use/User's Manual is attached in Appendix B, which contains detailed instructions.

5.15 Technological Characteristics Summary

The following Summary Information refers to the Norfolk Medical NorPort CT·PC Port and catheter, and the Lucent Non-coring needle

Is the new device compared to Marketed Device?

- Yes, the Norfolk Medical NorPort CT·PC Port and catheter, and the Lucent Non-Coring needle Infusion Set are compared to legally marketed predicate devices.

Does the new device have the same indications for use statement?

- Yes, the Norfolk Medical NorPort CT·PC Port and catheter, and the Lucent Non-coring needle have the same Indications For Use statement to legally marketed predicate devices.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. in deciding, impact on safety and effectiveness may be considered)?

- No, the differences do not alter the intended use of the port.

Does the new device have the same technological characteristics, e.g. design, materials, etc?

- No, not in all regards. The NorPort CT·PC Port implanted Port has some minor differences from the predicate devices, however, the fundamental scientific technology of the port/catheter has not changed.

The Lucent Non-coring needle infusion set has some minor differences from the predicate devices, however, the fundamental scientific technology has not changed.

Could the new characteristics affect safety and effectiveness?

No, there are no new significant characteristics that would affect safety and effectiveness in the new device.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes, FDA, Guidance on 510(k) Submissions for Implanted Infusion Ports, dated October 1990 was used to as a reference for the performance testing.

BS EN ISO 10555-1:2009, Sterile, single-use intravascular catheters Part 1:General requirements, was used as a testing reference.

ISO 11135-1:2007, Sterilization of health care products -Ethylene oxide- Part 1, Requirements for development, validation and routine control of a sterilization process for medical devices. Specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices.

ISO 10993-7: 2008, Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals.

ISO 14971: 2007, Medical Devices- Application of Risk Management to Medical Devices.

Are performance data available to assess effects of new characteristics?

Yes, verification testing was performed according to protocols based on the above referenced guidance document recommendation and additional standards, with positive performance examination results available as objective evidence in each category.

Do performance data demonstrate equivalence?

Yes, performance data gathered in the design verification testing demonstrated that the NorPort family of products is substantially equivalent to the predicate devices mentioned in this submission.

5.16 Non-Clinical Data

The data collected from the non-clinical tests demonstrated that the functionality and performance characteristics of the NorPort CT·PC implanted vascular port and the Lucent Non-coring needle infusion set are comparable to the currently marketed vascular ports and power capable needles. The tests performed include: catheter to port connection, septum puncture/port leak, patency verification, and high pressure static testing.

5.17 Conclusion

The NorPort CT·PC Port and the Lucent Non-coring Needle Infusion Set have met all predetermined acceptance criteria of design verification evaluations through testing examination. Based on the FDA's decision tree, it is logically concluded through evidence that the above mentioned medical devices are substantially equivalent to the predicate devices: Norfolk Medical NorPort 510 (k)#102385, 2010; the Angiodynamics SmartPort CT Port Access System 510 (k)#081472, 2008, the Smiths Medical PORT-A-CATH Titanium Venous Access System 510 (k)# 070116, 2007, the Bard PowerPort Implanted Titanium Port Chronoflex with 8 Fr. Catheter 510 (k)# 060812, 2006, the MEDCOMP ProFUSE Port 510 (k)# 070003, 2007, the PHS Medical C-Port 510 (k)# 091099, 2009 and the Norfolk Medical NorPort 510 (k)# 102385, 2010; Smiths Medical Gripper Plus Power P.A.C Needle (510 (k)# 070116), the Angiodynamics Lifeguard CT Safety Infusion Set (510 (k)#072375), the Bard PowerLoc Clear Safety Infusion Set (510 (k)# 082306), and the MEDCOMP CT Injectable Safety Non- coring Needle (510 (k)# 080544).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael J. Dalton
President
Norfolk Medical
7350 North Ridgeway
Skokie, Illinois 60076

AUG 25 2011

Re: K111101
Trade/Device Name: Lucent Non-coring Needle, Huber Needle Intravascular Administration Set-FPA, Nor-Port CT-PC (Family of Implanted Vascular Access Devices) Port and Catheter, Implanted, Subcutaneous, Intravascular-LJT
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: August 9, 2011
Received: August 10, 2011

Dear Mr. Dalton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Norfolk Medical

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Section 4

510(k) Number: _____

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111101

Device Name:

Lucent Non-coring Needle, Huber Needle Intravascular Administration Set-FPA

Needle Set:

The Lucent Non-coring needle set is intended for the administration of fluids and drugs as well as blood sampling through implanted vascular ports.

When used with the NorPort CT·PC Family of Implanted Vascular Access Device is also indicated for power injection of contrast media into the central venous system. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 and 20 gauge non-coring power injectable needle and 2 ml/s with a 22-gauge non-coring power injectable needle.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/20/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111101

Norfolk Medical

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____ **Section 4**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111101

Device Name:

NorPort CT-PC (Family of Implanted Vascular Access Devices) Port and Catheter, Implanted, Subcutaneous, Intravascular-LJT

Catheter /Port:

The NorPort CT·PC Family of Implanted Vascular Access Devices is indicated for use when the patient requires the following: repeated access to the vascular system for injections, infusion of drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen.

When used with a appropriately labeled power injectable needle infusion set, the NorPort CT·PC Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 and 20 gauge non-coring power injectable needle and 2 ml/s with a 22-gauge non-coring power injectable needle.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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